DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 5, 2015

Besmed Health Business Corp
c/o Paul Dryden
Consultant
No. 5, Lane 116, Wu-Kong 2nd Rd.
New Taipei City, Wu-Ku District
Taiwan

Re: K143150
Trade/Device Name: Besmed CO_2 Monitoring Line With and Without In-Line Filter
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: January 6, 2015
Received: January 7, 2015

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K143150

Device Name

Besmed CO_2 monitoring line with and without in-line filter

Indications for Use *(Describe)*

CO_2 Monitoring Lines are intended to connect from a CO_2 sampling port to the expired gas monitor.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Date Prepared: 30-Oct-2014

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Official Contact: Winnie Chung, Regulatory Affairs

Proprietary or Trade Name: Besmed CO_2 monitoring line with and without in-line filter

Common/Usual Name: CO_2 Monitoring Line

Classification Name: 21CFR 868.1400
CCK – Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
Class II

Predicate Devices: K122075 – Intersurgical – CO_2 Monitoring Line

Device Description:
The Besmed CO_2 monitoring line with and without in-line filter is single use, small diameter tubing intended to be connected to a port on a face mask or breathing circuit to allow for gas sampling from a patient's breath by gas sampling equipment. The gas monitoring device will have a pump, which pulls air from inside mask through the monitoring line and into the gas monitoring equipment. The monitoring line is available with or without a hydrophobic filter, which prevents the transfer of water down the monitoring line and into the gas sampling equipment. Lines are available with male/male or male/female luer connections. The patient connectors incorporate a midstream gas sampling port and are made of clear rigid plastic.

Indications for Use:
CO_2 monitoring lines are intended to connect from a CO_2 sampling port to the expired gas monitor.

Patient Population:
There is no specific patient population associated with this device. The clinician makes a decision as to whether to sample expired gases. This is independent of patient population. The predicate, K122075, used the following language for its patient population: "Any patient from which gas monitoring is required."

Environments of use:
Hospital and Sub-acute Institutions

Substantial Equivalence Discussion:
Table 5.1 compares the key features of the proposed Besmed CO_2 monitoring line with and without in-line filter with the identified predicate and demonstrates that the device can be found to be substantially equivalent. In summary one can conclude that substantial equivalence is met based upon the following:

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Table 5.1 – Predicate Comparison

Attribute	**K122075** **Intersurgical– CO_2 Monitoring Line with and without in-line filter**	**Proposed** **Besmed CO_2 Monitoring Line with and without in-line filter**
Intended use		
Indications for Use	CO_2 monitoring lines are intended to connect from a CO_2 sampling port to the expired gas monitor.	CO_2 monitoring lines are intended to connect from a CO_2 sampling port to the expired gas monitor.
Target Population	Any patient from which gas monitoring is required	Any patient from which gas monitoring is required
Environment of use	Hospitals and sub-acute care	Hospitals and sub-acute care
Single use	Yes	Yes
Design and performance		
Resistance to flow without in-line filter	13.54 mbar at l00 mL/min flow 37.61 mbar at 300 mL/min flow	8.47 mbar at l00 mL/min flow 24.35 mbar at 300 mL/min flow
Resistance to flow with in-line filter	25.21 mbar at l00 mL/min flow 61.92 mbar at 300 mL/min flow	11.96 mbar at l00 mL/min flow 33.59 mbar at 300 mL/min flow
Leakage	<1.0mL/min	<1.0mL/min
Connectors	2 x luer lock connectors	2 x luer lock connectors
Outer diameter	3.05mm	3.0mm
Inner diameter	1.47mm	1.5mm
Performance Testing	Resistance to flow ISO 594-2 luer fittings	Age Testing Pre and post- exposure Environmental Testing Luer fitting Resistance to flow ISO 594-2 luer fittings
Principle of operation	Gas is pulled from one end of the tube to the other by a pump in the gas sampling device	Gas is pulled from one end of the tube to the other by a pump in the gas sampling device
Compatibility	Designed for use with gas monitoring device (for example a Capnograph) with luer connections to gas sampling tubing	Designed for use with gas monitoring device (for example a Capnograph) with luer connections to gas sampling tubing
Materials	PVC (sample tubing) PC (luer connectors) Hydrophobic filter	PVC (sample tubing) PC (luer connectors) Hydrophobic filter
Biocompatibility	ISO 10993	ISO 10993 No direct or indirect patient contact
Packaged	Non sterile	Non sterile

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Indications for Use –
The indications for use are identical for the proposed device when compared to the predicate – K122075 – Intersurgical – CO_2 Monitoring Line.
Discussion – Each device is intended to connect from a CO_2 sampling port to the expired gas monitor.

Technology and construction –
The design, components, shape, size, etc. are equivalent to the predicate – K122075 – Intersurgical CO_2 Monitoring Line.
Discussion – Both the proposed device and the predicate are similar in design, construction, and materials.

Environment of Use –
The environments of use are identical to predicate - K122075 – Intersurgical – CO_2 Monitoring Line.
Discussion – The environments of use are identical to the predicate - K122075 – Intersurgical – CO_2 Monitoring Line.

Patient Population –
There is no specific patient population associated with this device. The predicate, K122075, used the following language for its patient population: "Any patient from which gas monitoring is required."
Discussion – The patient populations are equivalent to the predicate – K122075 – Intersurgical – CO_2 Monitoring Line.

Non-Clinical Testing Summary –
We performed a number of tests including comparative resistance to flow and the results demonstrated equivalent performance, which is discussed in details in Section 18 – Performance - Bench demonstrating the proposed device is equivalent to the – K122075 – Intersurgical CO_2 Monitoring Line.
The following tests were performed:

- Flow resistance
- Age and Environmental Testing
    - Pre and post- exposure
    - Luer fitting tests (ISO 594-2)

Clinical Testing –
No clinical testing was required or performed.

Substantial Equivalence Conclusion:
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.